JENNIFER PANAGOULIAS

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF NEW YORK

UMB BANK, N.A., as Trustees

Plaintiff

v.

Civil Action No.

15 Civ. 08725(GBD)

SANOFI

Defendant

_____/

C O N F I D N E N T I A L

VIDEOTAPED DEPOSITION OF

JENNIFER PANAGOULIAS

Boston, Massachusetts

Wednesday, November 1, 2017

Reported by:

Deborah Roth, RPR-CSR

Job No. 130152

affairs.

Q. So your regulatory affairs coursework, in that course, did they provide you materials, you know, did that organization provide you materials and guidance as part of that course?

A. Yes. Yes.

Q. And was that through the organization that certified you or through Northeastern?

A. That was through Northeastern.

Q. So it was Northeastern material and not from the regulatory entity that ultimately issued the certificate?

A. It was -- no, it was not the institute that issued the certificate.

Q. And can you briefly -- can you go over your professional history, starting post college?

A. Post college, I work for a few years in two different law firms in Boston as a paralegal assistant before transitioning into regulatory affairs in 1998.

Q. And what was your first role in regulatory affairs?

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A. I was the assistant to the head of the regulatory affairs department at the time.

Q. The regulatory affairs department -- were you with Genzyme?

A. At Genzyme.

Q. Okay. So you've been at -- you started at Genzyme beginning in 1998?

A. That's correct.

Q. Okay. And how have you -- how, if at all, did your positions change after you began at Genzyme?

A. I started as the assistant, and I was in that role for, I believe, six months, and then I was promoted to a regulatory affairs operations associate, and I began working in an operational capacity, to support publication of submissions, INDs and BLAs, for various product lines through the company.

From that I progressed to an associate position, where I had responsibility for development programs in the rare disease unit, and I continued in various capacities, where I progressed

through, you know, different levels, if you will, at Genzyme, until I left the organization in 2015, at which time I was associate vice president and therapeutic area head for MS Neurology.

Q. And in your -- why did -- when did -- or sorry, withdrawn.

Why did you leave Sanofi Genzyme in 2015?

A. I think I had been there for 17 years, and I thought that my career would benefit from having some other experiences at different companies, working in either various therapeutic areas or just understanding different company culture.

Q. And where did you work next?

A. Alnylam.

THE COURT REPORTER: I'm sorry?

THE WITNESS: Alnylam.

Q. Sorry. I'm sure I have the information.

What did you do in your next role?

A. I was a regulatory -- global regulatory affairs lead for several of their

She did not have a counterpart, um, at Sanofi, because the organization was structured I think differently at Sanofi, but there was a head of global regulatory affairs for the entire Sanofi group.

Q. And who was that person at the time Ms. Williamson left?

A. Hilary Malone.

Q. And was there -- who was the person who filled that role prior to Ms. Malone having that position?

A. Richard Gural.

Q. So can you discuss your role with respect to the drug alemtuzumab at Genzyme?

MR. NEUWIRTH: Objection to the form.

You can answer that to the best of your ability.

A. My role in regulatory affairs?

Q. Yes.

A. I was responsible for global regulatory strategy, leading to the registration of Lemtrada.

Q. So was that always your role or

did that become your role at a particular time?

A. It became my role in 2009.

Q. So prior to 2009, what was your responsibility with respect to the alemtuzumab?

A. I had very limited involvement before 2009.

I was working prior to 2009 in the rare disease group, and I had responsibility for the development of Myozyme and Lumizyme and other products for Pompe disease within Genzyme. And for a short time in 2006 I covered for the individual that was responsible for Lemtrada while she was on maternity leave. So for approximately three to four months I helped out while she was away.

Q. So was -- in 2009, when you started working on the alemtuzumab, was that your first exposure to a multiple sclerosis drug?

A. And what do you mean by "exposure"?

Q. Professional work concerning the potential approval of a multiple sclerosis

[redacted]

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[redacted]

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Is your testimony that EDSS had components of which were subjective?

A. Yes.

Q. And were there other endpoints that were objective?

A. MRI was an objective endpoint.

Q. Any others that you recall?

A. We had -- all of the pharmacodynamic endpoints are objective.

[redacted]

[redacted]

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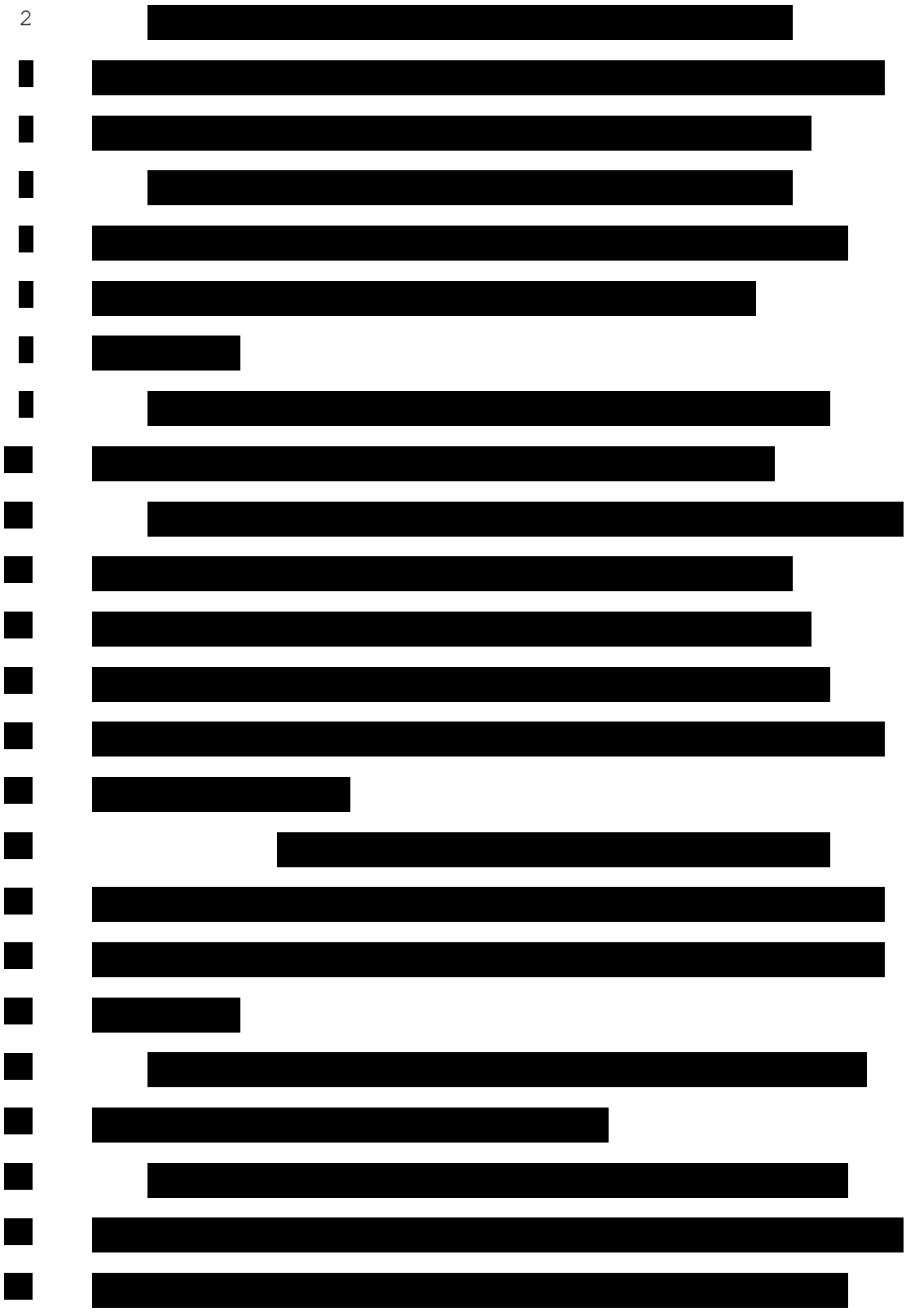

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[redacted]

Q. I am going to hand you what has been previously marked Plaintiff's 33.

(Exhibit 33 was introduced.)

Q. And these are the meeting minutes from the March 10, 2014, Type A meeting, correct?

A. Uh-huh.

Q. You can take a look and let me know when you're ready to discuss.

A. (Witness reviews document.)

Uh-huh.

[redacted]